



Lab Working Group Meeting
Los Angeles, California
July 29, 2004

Members:

John Eckfeldt, Chair, University of Minnesota
Jim Fleming, LabCorp
Elisa Gladstone, NIDDK
Thomas Hostetter, NIDDK
Harvey Kaufman, Quest Diagnostics
Tim Larson, Mayo Clinic
Greg Miller, Virginia Commonwealth University
Gary Myers, CDC
Mauro Panteghini, IFCC, Brescia University Hospital
Michael Welch, NIST

Guests:

Dave Armbruster, Abbott Laboratories
Sharon Burr, College of American Pathologists
Richard Miller, Dade Behring
David Secombe, Canadian External Quality Assessment Lab
Dietman Stocke, University of Ghent
Linda Thienpont, University of Ghent

NIST Reference Materials:

- Greg Miller will send Mike Welch key points about changes that need to be made to the temperature at which clotting takes place.

Update on NIST Reference Material Commutability Testing

- John Eckfeldt will begin collection, aliquotting and freezing of serum specimens from outpatients seen in their renal transplant evaluation and diabetes clinic for this purpose.
- Mike Welch agreed to analyze one of the aliquots by their new ID-LCMS method.

Update on CAP New Linearity Survey

- John Eckfeldt and Sharon Burr will arrange for reference method analysis of the master pools of the LN24 pilot at NIST

- John Eckfeldt and Sharon Burr will arrange for reference method analysis of the master pools of the actual LN24 samples that will be prepared this fall at both NIST and Linda Theinpont's laboratory.

Comments from the Manufacturers' Forum

- Greg Miller will develop a summary of the issues raised during the forum and will send to working group members for comment. Key comments included:
 - Timing and sequence of events is critical and must be communicated clearly
 - Concern about impact on proficiency testing. PT providers are a key target audience for communications.
 - NKDEP should work with CMS to help them understand the situation and timeline for improved creatinine.
- Have a separate conference call dedicated to working out the timeline and sequence of events.
- Once the summary is complete, Elisa Gladstone will post the summary and the slides to the NKDEP website. NKDEP will invite manufacturers to visit the website and provide additional feedback. Elisa will email an announcement to Rick Miller and Mauro Panteghini to put on the AACC Industry Division and IFCC's websites respectively.
- To help identify how many labs are reporting estimated GFR, we will try to add a question to the CAP survey. The group discussed adding a clinical vignette requiring a GFR calculation. Sharon Burrs will talk to the advisory committee about adding a question.
- Greg Miller will take responsibility for developing the question.
- NKDEP should also try to get data from the CAP Excel program regarding physician offices and small hospitals.

Biological Variability of Creatinine v. Creatinine Clearance v.GFR

- Tom Hostetter will get data from DCCT and MDRD related to biological variability. He will ask Andy Levey to identify other sources of data.

Review Current Draft of Manuscript

- Comments included:
 - The group decided that there will be only one paper, which will be a state of the art paper that includes the Work Group's recommendations. Perhaps we should have an editorial summary that (hopefully) supports the recommendations. We will need the journal editor to buy into that approach.
 - Add page numbers.
 - Add a title.
 - Need to redo the biological variation section.
 - Reference the CAP paper and Dave Seccombe's manuscript once they are available. Will strengthen the document.
 - Add some limitations into the introduction section.

- With recommendations, may be appropriate to identify or suggest organizations to do the work. This can be used to help justify funding and support.

Other

- Discuss whether NKDEP wants to develop a National Academy of Clinical Biochemistry monograph providing clinical guidelines for using creatinine.
- Elisa will circulate the website so members can review previous monographs.
- The question remains whether the information that is published in *Clinical Chemistry* can be published in the monograph as well.

Next Meeting

- NKDEP will canvas the group by email to identify a convenient time for our next conference call.